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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,303	02/18/2004	Rafail Zubok	532-3X9a	4832
530 7590 05/12/2008 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090				
EXAMINER WOODALL, NICHOLAS W				
ART UNIT 3733		PAPER NUMBER		
MAIL DATE 05/12/2008		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/781,303

Applicant(s)

ZUBOK ET AL.

Examiner

Nicholas Woodall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-5 and 7-15 is/are rejected.
7) ☒ Claim(s) 6 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-946)
3) ☒ Information Disclosure Statement(s) (PTO/CIS)
Paper No(s)/Mail Date 11/05/2007.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to applicant's amendment received on 02/07/2008.

Claim Objections

2. Claims 1, 3, and 5 are objected to because of the following informalities: claims 1, 3, and 5, positively recited elements from the intervertebral disc replacement device, which is functionally recited in the preamble of claim 1. For example, claim 1 states,... one lateral flange partially received over a portion of said bone screw.... The examiner is unclear if the claims are directed to the subcombination, i.e. the retaining clip, or the combination, i.e. the retaining clip and the intervertebral replacement device. The examiner will interpret the claims as being directed to the subcombination for examination purposes. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

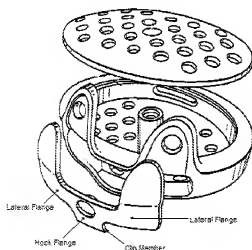
4. Claims 1 and 2 are rejected as understood under 35 U.S.C. 102(b) as being anticipated by Bray (U.S. Patent 5,888,223).

Regarding claim 1, Bray discloses a device comprising a body member. The body member includes a first side, a hook flange, and two lateral flanges (see Figure 1 below). The hook flange extends from the body member in a first direction capable of clipping retention of the first side of the body member against a flange of an

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intervertebral disc replacement device, wherein at least one surface of the hook flange opposes the first surface of the body member. The two lateral flanges extend from the body member in opposite directions that are perpendicular to the first direction capable of being partially received over a portion of a bone screw to prevent the bone screw from backing out of an intervertebral replacement device.

Figure 1



Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3-5 and 7 are rejected as understood under 35 U.S.C. 103(a) as being unpatentable over Bray (U.S. Patent 5,888,223) in view of LeHuec (U.S. Patent 6,884,242).

Bray discloses a device as discussed above wherein the hook flange further comprises a clip member, for example the curved tip portion of the hook flange, protruding therefrom in a direction toward the first side of the body member capable of being received in a recess of an intervertebral replacement device. The examiner is interpreting the curvature of the curved tip portion to be in a direction toward the first side because the first side also includes the curved portions of the lateral flanges. Bray further discloses the device comprising a connection mechanism including a screw inserted through a bore of the device capable of being inserted into a mounting hole of an intervertebral replacement device in order to attach the device to an intervertebral replacement device (column 5 lines 26-27). LeHuec teaches a device comprising a retaining device including a connection mechanism including a substantially circular protrusion (for example elements 137, 138, and 140) extending from a first side of a body member capable of being snapped into engagement with a substantially circular mounting hole of an intervertebral replacement device in order to attach the retaining device to an intervertebral replacement device. Because both Bray and LeHuec disclose devices including a connection mechanism, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one connection mechanism for the other in order to achieve the predictable results of attaching the retaining device to an intervertebral replacement device.

7. Claims 8-14 are rejected as understood under 35 U.S.C. 103(a) as being unpatentable over March (U.S. Patent 4,217,902) in view of Powers (U.S. Publication 2005/0033430).

March discloses a device comprising an applicator and at least one retaining clip. The applicator comprising a first applicator arm and a second applicator arm, wherein the applicator arms extend in substantially the same direction from a common bending elbow (see Figure 2 below). The applicator arms further include a protrusion capable of being secured with an opening in the retaining clip. The retaining clip comprises a body member having a first side, a hook flange, and at least one lateral flange. The hook flange extends from the body member in a first direction. The at least one lateral flange extends from the body member in a second direction perpendicular to the first direction (see Figure 3 below). March fails to disclose the device further comprising an enclosure and a second retaining clip attached to the second applicator arm. Powers teaches an enclosure capable of holding a set of sterilized surgical instruments that is made from a non-permeable material, such as plastic (page 2 paragraph 021) and the enclosure being sealed and devoid of substantially moist air by using a seal or cover that is removably attached to the enclosure (page 2 paragraph 023) in order to maintain the sterility of the surgical instruments until such a times as the instruments are to be assessed (page 2 paragraph 020). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of March further comprising an enclosure in view of Powers in order to maintain the sterility of the surgical instruments until such a time as the instruments are to be assessed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of March having a plurality of retaining clips, since it has

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been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Figure 2

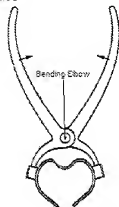
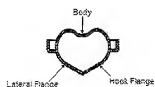


Figure 3



8. Claim 15 is rejected as understood under 35 U.S.C. 103(a) as being unpatentable over Rygg (U.S. Patent 3,278,107) in view of Powers (U.S. Publication 2005/0033430).

Rygg discloses a device comprising an applicator and at least one retaining clip. The applicator includes a first applicator arm and a second applicator arm extending in substantially the same direction from a common bending elbow. The at least one

retaining clip includes a body member having a first side, a hook flange extending from the body member and at least one lateral flange extending from the body member.

Rygg discloses the device comprising a cartridge of retaining clips, wherein the inserter arms are secured to the outermost retaining clip, such as the first retaining clip, while the retaining clip is still secured within the cartridge. At this time, all the retaining clips are simultaneously removably secured to the applicator arms via the retaining clip cartridge. Rygg fails to disclose the device further comprising an enclosure. Powers teaches an enclosure capable of holding a set of sterilized surgical instruments that is made from a non-permeable material, such as plastic (page 2 paragraph 021) and the enclosure being sealed and devoid of substantially moist air by using a seal or cover that is removably attached to the enclosure (page 2 paragraph 023) in order to maintain the sterility of the surgical instruments until such a time as the instruments are to be assessed (page 2 paragraph 020). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Rygg further comprising an enclosure in view of Powers in order to maintain the sterility of the surgical instruments until such a time as the instruments are to be assessed.

Allowable Subject Matter

9. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

10. Applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection. Regarding the applicant's argument that the examiner and his supervisor agreed the language amended into claim 15 constitutes allowable subject matter is not persuasive. First, the examiner would like to note that the examiner and his supervisor stated that the language appeared to overcome the prior art rejection but further consideration would be needed prior to declaring the subject matter allowable. Secondly, the Rygg reference discloses a device comprising an applicator and a retaining clip as discussed above and in the previous rejection, wherein the retaining clips are secured within a retaining clip cartridge. The applicator arms are secured to the outermost retaining clip while the retaining clip is still secured to the retaining clip cartridge. Therefore, all the retaining clips are simultaneously removably secured to the applicator arms via the retaining clip cartridge. The examiner has presented new grounds of rejection as necessitated by the amendment making this office action **FINAL**.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733